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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,196	12/03/2001	Mai Shen-Chih	6653-016-999	4434

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EXAMINER	
KAUFMAN, CLAIRE M	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,196	SHEN-CHIH ET AL.	
	Examiner	Art Unit	
	Claire M. Kaufman	1646	

-- The MAILING DATE of this communication app ars on th cover she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 24-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 11-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5/9/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the paper filed 8/18/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double

patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claim Objections

Claim 4 is objected to because of the following informalities: in line 2, "a immunoglobulin" should be "an...". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 11-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The hybridomas in the instant claims are referred to by name only. The name 3H5 appears as the name of antibodies in the prior art, though the name of the hybridoma producing each prior art antibody is unknown (see for example, Littaua et al., J. Immunol. 144:3183, 1990, and Medvedev et al., Eur. J. Immunol. 24:2842, 1994). As a result, the claims are unclear because the same name has been used multiple times to refer to different antibodies. This rejection could be overcome by modifying the antibody name with the unique CCRC number under which it is deposited. For example, "Hybridoma 3H3 deposited under accession number CCRC 960123...."

Claims 1, 2, 6 and 7 are indefinite because they use the term "against" (line 2). While antibodies may be generated by injecting an antigen into an animal, *i.e.*, making antibodies against the antigen, not all antibodies generated will bind the antigen. Therefore, use of the term "against" makes the claims unclear. This rejection could be obviated by rephrasing the claims such as "...a monoclonal antibody which binds ~~against~~ decoy receptor 3...." or "an anti-DcR3 (decoy receptor 3) ~~a~~ monoclonal antibody ~~against decoy receptor 3~~...."

Claim 11 is indefinite because it is unclear if the "means for signal generation, which can be operably linked with said monoclonal antibody...," **is** actually linked or is **optionally** linked. This rejection could be obviated by rephrasing the claim as follows: "means for signal generation, which is ~~can be~~ operably linked with said monoclonal antibody

Claim 15 is indefinite because an immunoassay is not a signal, it is a means of detecting a signal. Just as "luminescent label and enzyme" are used in the claim, "radioactive label and fluorescent label" could be likewise used to obviate this rejection.

Claim 12 is indefinite because it is unclear if all three means of support are selected from the 4 listed materials or only the protein immobilizing material is. If the former is intended, wording such as '...material, wherein the included means for support are selected from the group consisting of....' could clarify the claim. If the later is intended, wording such as '...material, which immobilizing material is selected from the group consisting of....' could clarify the claim.

Claim 16 is indefinite because the luminescent label (line 1) must *be* a label and cannot *include* a label. This rejection could be obviated by using phrasing such as "the luminescent label is a ~~includes~~ biological...."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 11-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Elements required for practicing a claimed invention must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. When biological material is required to practice an invention, and if it is not so obtainable or available,

the enablement requirements of 35 USC §112, first paragraph, may be satisfied by a deposit of the material. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining hybridoma 3H5 or 9!10C3, and it does not appear to be a readily available material even though it was deposited with the Culture Collection and Research Center of Food Industry Research and Development Institute (Hsinchu Taiwan) on October 11, 2000. The reasons this deposit does not satisfy the requirements of 35 USC §112, first paragraph, is that the address of the depository (233, Shih-Pin Road, Hsin Chu City,Taiwan, Republic of China) is needed as is a declaration or statement including that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in accordance with the requirements set forth below (see 37 CFR 1.803-1.809).

For each deposit made pursuant to these regulations, the specification shall contain: (1) The accession number for the deposit; (2) The date of the deposit; (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and (4) The name and address of the depository. [See MPEP 2404-2410.02]

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or Declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-1.809 for additional explanation of these requirements.

Claims 11-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a kit for detection of the DcR3-associate diseases selected from the group consisting of: nasopharyngeal cancer, head and neck cancer, lung cancer, breast cancer, colon cancer, transitional epithelial cancer, hepatic cancer, esophageal cancer, leukemia, lupus erythematosus, hepatitis B, acquired immunity deficiency syndrome, and asthma as defined in the specification (p.16, lines 20-22) for a patient who had total IgE levels higher than 250 kU/L, does not reasonably provide enablement for detection wherein the DcR3-associated disease are selected from the group consisting of: allergies, autoimmunity diseases (other than AIDS) and any hemo-disease and cancer caused by viral infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are narrow in scope when referring to particular cancers and conditions, but are very broad when including allergies, autoimmunity diseases (other than AIDS) and any hemo-disease and cancer caused by viral infection. Even though asthma sufferers with total IgE levels higher than 250 kU/L could be identified by this assay (see Fig. 4), one skilled in the art would not reasonably expect this detection to extend to all allergies. First, there are no examples of other allergies that are detectable with this kit. Second, allergies are diverse and not well understood. For example, it is not uncommon for children who are allergic to peanuts to also have asthma. However, not all asthmatic children have peanut allergies or *vise versa*. There is no information in the specification to give the skilled artisan a reasonable expectation that the detection kit would detect those patients who suffer from peanut allergies but are not asthmatic. Similarly, asthma is a distinct disease though sometimes occurs in patients with environmental allergies (*e.g.*, dust mites or pollen). Again, there is no reasonable expectation that the claimed

kit could be used to detect environmental allergies, drug, latex, food or other allergies. While allergic reactions are typified by the presence of particular IgEs which bind particular allergens (*e.g.*, Figs. 24-1 and 24-2 of Stites et al.), there is no guidance in the instant specification to indicate that detection of IgE in asthma patients is representative of detection of IgE in any allergy-suffering patient.

Similarly autoimmune diseases have varied causes and symptoms. The jump from detection of AIDS in patients to the ability to detect any an autoimmune disease is not supported by the specification. Autoimmune disease range from potentially hereditary diseases such as Hashimoto's thyroiditis (*ibid.*, paragraph bridging pages 413-414) to those stemming from antigen cross-reactivity to those caused by infection leading to inflammation and a cascade causing aberrant major histocompatibility complex molecules (*e.g.*, *ibid.*, p. 412). Likewise, there is no support in the specification for detection of any hemo-disease or cancer caused by a virus. The examiner is not aware of a recognized and reliable tie between viral infection and resulting cancer in the prior art. Further, the showing of detection of a species of the broadly recited diseases does not support detection of the genus encompassed.

For the reasons above and for the reasons which include the complex, varied and/or unknown causes of allergies, autoimmunity diseases, hemo-diseases and cancers, the complex expression of these diseases, the lack of working example to support detection for the broad range of diseases encompassed by the claims, the lack of guidance and information in the specification linking these diseases so that the skilled artisan would reasonably expect detection of one would be predictive of detection of another, the breadth of the diseases recited, and the lack of information in the prior art about the origin/cause of the diseases and expression of DcR3 or any other death domain-related receptor, it would require undue experimentation to practice the claimed invention commensurate in scope with the claims.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim requires that the hybridoma produced by immunization with DcR3 and an immunoglobulin constant region (Fc) to have an Fc obtained from human G1 immunoglobulin. However according to the specification, the hybridomas were selected to include only those which recognized human dcR3 and not human G1immunoglobulin Fc portion. Therefore, it appears that the claimed hybridoma does not have the Fc portion required by the claim (p. 13, lnes 18-22).

Conclusion

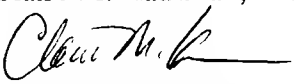
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791 (changing to (571)272-0873 on 01/21/04). Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564 (changing to (571)272-0871 on 01/21/04).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 872-9306. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

November 24, 2003